October 19, 2021

Capsule Technologie SAS
Peter Kelley
Director Quality, Regulatory & Cybersecurity
76 - 78 Avenue de France
Paris, 75013
France

Re: K210204
Trade/Device Name: Capsule Vitals Plus Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, FLL, CCK
Dated: September 14, 2021
Received: September 15, 2021

Dear Peter Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210204

Device Name
Capsule Vital Plus Patient Monitoring System

Indications for Use *(Describe)*
The Capsule Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Per 21 CFR 807.92

Submitter's Name and Address	Capsule Technologies, SAS 76-78 avenue de France Paris, France 75013
Contact Name and Information	Peter Kelley Director Quality, Regulatory & Cybersecurity Capsule Tech, Inc 300 Brickstone Square, Suite 203 Andover, MA 01810 Phone: 978-697-4364 e-mail: pkelley@capsuletech.com
Date Prepare	January 22, 2021
Device Trade Name	Capsule Vitals Plus Patient Monitoring System
Common Name	Physiological or Vital Signs Monitor, Patient Monitor
Class and Classification Name	Class II, 21 CFR Part 870.2300 – Cardiac monitor (including cardiotachometer and rate alarm)
Product Code	MWI, DXN, DQA, FLL, CCK
Predicate Devices	SmartLinx Vitals Plus Patient Monitoring System, K200856. Cleared July 10, 2020.

Device Description

The predicate device, the SmartLinx Vitals Plus Patient Monitoring System, was cleared in K200856.

The Capsule Vitals Plus Patient Monitoring System which is the subject of this submission is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by.

It operates with the Capsule Medical Device Information Platform (CMDIP) a Medical Device Data System to present patient information to the clinical user for active monitoring purposes at the point of care.

The proposed Capsule Vitals Plus Patient Monitoring System consists of the following components:

- Capsule Neuron Mobile Platforms
- Capsule Vitals Plus Application
- Capsule Vitals Plus NIBP Monitoring Modules
- Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02
- Capsule Capnography Interface Module
- Nellcor SpO2 Oximetry Module
- Masimo uSpO2 Pulse Oximetry Cable
- Exergen TAT-5000S Temperature Scanner
- Capsule Early Warning Scoring System

SmartLinx Neuron Mobile Platform – Neuron 2

The SmartLinx Neuron (Neuron 2) is a mobile computer which utilizes industry standard PC architecture and components, with touch-screen capabilities, and serial, USB, network, and RFID interfaces and which runs a Microsoft Windows operating system. It is used by healthcare providers through the applications running on it, and it is accessed by IT administrators during management and maintenance. The Neuron 2 provides connectivity to medical devices through isolated serial and USB ports. It also communicates with other IT systems through Ethernet or Wi-Fi network connections. The Neuron 2 is IEC 60601-1 compliant for use in Medical Electrical Systems. The Neuron 2 is utilized as part of an active monitoring system when running the SmartLinx Vitals Plus Application. The Neuron 2 is unchanged from the predicate device.

Capsule Neuron Mobile Platform – Neuron 3

A new version of the Neuron Mobile Platform (Neuron 3) is being added to the Vitals Plus Patient Monitoring System, in addition to the Neuron 2 of previous 510(k) submissions. Neuron 3 was developed and released under a separate program which was primarily driven by a CPU update. The Neuron 3 is now being added to the Vitals Plus Patient Monitoring System.

The design changes introduced with the Neuron 3 are:

- A new touch screen that uses capacitive versus resistive technology.
- A new display screen that uses a glossy display versus a matte display.
- Incorporating the primary audio alarm mechanism and the watchdog functionality which was formerly implemented in the NIBP Monitoring Module. The new implementation of the primary audio alarm mechanism and the watchdog functionality re-uses the same electrical design as before, except with a new speaker.
- Update the operating system to Windows 10.

Capsule Vitals Plus Application

The Capsule Vitals Plus Application is a mobile medical application operating on the Capsule Neuron. The Vitals Plus Application controls the externally integrated vital signs modules through interfaces on the Neuron and the Vital Plus NIBP Monitoring Modules and presents patient information to the user for active monitoring purposes at the point of care. The supported physiological parameters are: NIBP (systolic, diastolic, mean arterial pressure (MAP), pulse rate, SpO2, end-tidal and fractional concentration of inspired CO2, respiration, and temperature. This is unchanged from the predicate device.

The Vitals Plus Application has been modified to include a plethysmography wave display which is derived either from either the Nellcor SpO2 Oximetry Module or the Masimo uSpO2 Pulse Oximetry Cable.

SmartLinx Vitals Plus NIBP Monitoring Module for Neuron 2

The SmartLinx Vitals Plus NIBP Monitoring Module for Neuron 2 incorporates the SunTech Medical Advantage A+ OEM NIBP module and associated blood pressure cuffs and hoses. It measures systolic, diastolic and mean arterial blood pressures (MAP), and pulse rates for adult, pediatric and neonatal patients. The module is controlled by the SmartLinx Vitals Plus Application to manage the inflation and deflation of blood pressure cuffs, and to measure blood pressures and pulse rates. The SmartLinx Vital Plus NIBP Monitoring Module for Neuron 2 provides a primary speaker for alarm annunciations with failover to a secondary speaker, watchdog functionality, and a USB hub for expansion. The NIBP Monitoring Module for Neuron 2 is unchanged from the predicate device.

Capsule Vitals Plus NIBP Monitoring Module for Neuron 3

A new NIBP Monitoring module has been created that attaches to the Neuron 3 and moves the primary audio alarm mechanism and the watchdog functionality to the Neuron 3. The Neuron 3 NIBP Monitoring Module incorporates the backup alarm speaker which was formerly in the Neuron 2. The rest of the electrical design remains unchanged.

The NIBP Monitoring Module for Neuron 3 incorporates the same SunTech Medical Advantage A+ OEM NIBP module and associated blood pressure cuffs and hoses as the NIBP Monitoring Module for the Neuron 2. It measures systolic, diastolic and mean arterial blood pressures (MAP), and pulse rates for adult, pediatric and neonatal patients. The module is controlled by the Capsule Vitals Plus Application to manage the inflation and deflation of blood pressure cuffs, and to measure blood pressures and pulse rates. The Neuron 3 NIBP Monitoring Module uses the same SunTech NIBP cuffs as the unchanged Neuron 2 NIBP Monitoring Module.

The NIBP Monitoring Module for Neuron 3 provides a secondary speaker for alarm annunciations and a USB hub for expansion.

Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02

The Masimo NomoLine ISA™ CO2 Gas Analyzer is a sidestream analyzer intended to be connected to a host instrument for monitoring of CO2 and respiratory rate. NomoLine ISA CO2™ is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery, and respiratory care.

NomoLine sampling lines are intended to be used as accessories to the NomoLine ISA™ gas analyzers. They are connected to the nostrils or to the nostrils and mouth and of spontaneously breathing patients and are connected in-line with the airway adapters for sampling of CO2. These are single use accessories provided by the manufacturer and distributed by Capsule. They have met required shelf life criteria according to the K171121 Summary, and do not affect the shelf life of the subject device.

The Capsule Vitals Plus Application controls the operation of the ISA CO2 to measure CO2 and respiration rate in adult, pediatric, and neonatal patients which is unchanged from the predicate device. The Masimo NomoLine ISA CO2 analyzer is also unchanged from the predicate device.

Capsule Capnography Interface Module

The Capnography Interface Module (CIM) is an RS-232 serial to USB converter designed to Capsule's specification by a third party. It connects to the ISA CO2 module via a DB-9 connector and to the Neuron via a USB connector. It communicates with the Vitals Plus Application through a Device Driver Interface (DDI) developed by Capsule. The CIM is unchanged from the predicate device.

Nellcor SpO2 Oximetry Module

The Nellcor SpO2 Oximetry Module connects with Nellcor SpO2 Pulse Oximetry sensors and provides functional oxygen saturation (SpO2) and pulse rate and other information via a serial digital interface. The Capsule Vitals Plus Application controls the operation of the Nellcor SpO2 Oximetry Module to measure SpO2 and pulse rate in adult, pediatric, and neonatal patients.

Masimo uSpO2 Pulse Oximetry Cable

The Masimo uSpO2 Pulse Oximetry Cable is a cable with an integrated MS-2000 series circuit board contained in an enclosure that connects to Masimo pulse oximetry sensors and provides functional oxygen saturation (SpO2) and pulse rate and other information via a serial digital interface. The Capsule Vitals Plus Application controls the operation of the uSpO2 to measure SpO2 and pulse rate in adult, pediatric, and neonatal patients.

Exergen TAT-5000S Temperature Sensor

The Exergen TAT-5000S temperature sensor is designed for noninvasive temperature assessment by scanning the temporal artery. The thermometer operates independently but communicates its results to the Vitals Plus Application for display and monitoring.

Capsule Early Warning Scoring System

The Capsule Early Warning Scoring System (EWSS) is an optional software component that integrates with the Capsule Vitals Plus Application and runs on the Capsule Neuron. Capsule EWSS performs a medical calculation that aids clinical users in patient assessment and condition trending. This calculation, which would otherwise be completed manually, produces an aggregate patient score from a set of sub-scores determined from the values of measured vital signs and manually entered physiological observations. The resulting aggregate score is displayed on the Vitals Plus Application and may be communicated to other healthcare information systems. EWSS requires the clinical user to attend the patient in order to function. There is no automatic or continuous scoring. The specific scoring method used within Capsule EWSS to calculate a patient's score is determined by the customer.

Intended Use

The Capsule Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when

used by clinical physicians or appropriate medical staff under the direction of physicians.

Comparison of Similarities and Differences

This discussion of substantial equivalence follows the guidelines published in: *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications Guidance for Industry and Food and Drug Administration Staff July 28, 2014."* This submission uses one predicate device, the current SmartLinx Vitals Plus Patient Monitoring System (K200856). The proposed Capsule Vital Plus Patient Monitoring System is substantially equivalent to the predicate device, in terms of classification (Table 1), intended use (Table 2) and technical characteristics (Table 3), as described below.

Table 1 Comparison of Classification of Proposed Device to Predicate Devices

Attribute	Predicate SmartLinx Vitals Plus	Proposed Capsule Vitals Plus	Discussion
Manufacturer	Capsule Technologie, SAS	Capsule Technologie, SAS	Same as predicate
Regulation Number	870.2300	870.2300	Same as predicate
Regulation Name	Cardiac monitor (including cardiotachometer and rate alarm)	Cardiac monitor (including cardiotachometer and rate alarm)	Same as predicate
Product Codes	MWI, DQA, DXN, FLL, CCK	MWI, DQA, DXN, FLL, CCK	Same as predicate
510(k) Number	K200856	Pending	
Class	II	II	Same as predicate

Table 2 Comparison of Intended Use of Proposed Device to Predicate Devices

Intended Use / Indications for Use	
Proposed Capsule Vitals Plus	The Capsule Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.
Predicate SmartLinx Vitals Plus	The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), end-tidal and fractional concentration of inspired CO2, respirations, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.
Discussion	The proposed Capsule Vital Plus Patient Monitoring System intended use is the same as the predicate other than changing the brand name.

Table 3 Comparison of Technical Characteristics of Proposed Device to Predicate Devices

Attribute	Predicate Device: SmartLinx Vitals Plus	Proposed Device: Capsule Vitals Plus	Discussion
Design	Intervals Mode for NIBP (Automatic repetition of NIBP measurements): SmartLinx Vitals Plus NIBP Module using SunTech Advantage A+ oscillometric OEM NIBP module with intervals at 1, 2, 3, 4, 5, 10,15, 30, 60, 90, 120 and 240 minutes	Intervals Mode for NIBP (Automatic repetition of NIBP measurements): SmartLinx Vitals Plus NIBP Module using SunTech Advantage A+ oscillometric OEM NIBP module with intervals at 1, 2, 3, 4, 5, 10,15, 30, 60, 90, 120 and 240 minutes	Same as predicate
	SpO2 Measurement: Masimo or Nellcor Continuous SpO2 Monitoring: Pulse tone pitch, sensor off alarmSpO2 alarm delay: Selectable time (secs) for Masimo, SatSeconds for Nellcor	SpO2 Measurement: Masimo or Nellcor Continuous SpO2 Monitoring: Pulse tone pitch, sensor off alarmSpO2 alarm delay: Selectable time (secs) for Masimo, SatSeconds for Nellcor	Same as predicate
	Alarms: Configuration, annunciation, and acknowledgement of physiological (Sys, Dia, MAP, Pulse Rate, SpO2, and TEMP) and technical alarms	Alarms: Configuration, annunciation, and acknowledgement of physiological (Sys, Dia, MAP, Pulse Rate, SpO2, and TEMP) and technical alarms	Same as predicate
	TEMP: Exergen TAT-5000S temporal artery scanner thermometer	TEMP: Exergen TAT-5000S temporal artery scanner thermometer	Same as predicate
	CO2: Infrared spectroscopy	CO2: Infrared spectroscopy	Same as predicate
Applied Parts	NIBP: SunTech Durable One-Piece, Disposable, and Vinyl blood pressure cuffs and hoses, and GE CRITIKON SOFT-CUF cuffs	NIBP: SunTech Durable One-Piece, Disposable, and Vinyl blood pressure cuffs and hoses, and GE CRITIKON SOFT-CUF cuffs	Same as predicate
	SpO2: Masimo LNCS and Nellcor families of reusable and disposable SpO2 sensors	SpO2: Masimo LNCS and Nellcor families of reusable and disposable SpO2 sensors	Same as predicate

Attribute	Predicate Device: SmartLinx Vitals Plus	Proposed Device: Capsule Vitals Plus	Discussion
	Masimo® or Nellcor® SpO_2 algorithms (optional)—both sensors and signal processing	Masimo® or Nellcor® SpO_2 algorithms (optional)—both sensors and signal processing	Same as predicate
	TEMP: Exergen disposable probe covers and sheaths	TEMP: Exergen disposable probe covers and sheaths	Same as predicate
	CO2 Cannula: Soft PVC	CO2 Cannula: Soft PVC	Same as predicate
	Co2: Airway Adapter: Hard plastic; methyl methacrylate-acrylonitrite-butadiene-styrene (MABS)	Co2: Airway Adapter: Hard plastic; methyl methacrylate-acrylonitrite-butadiene-styrene (MABS)	Same as predicate
Energy Source	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh	Same as predicate
		Main Battery Neuron 3: Lithium-Ion 3S1P 3350 mAh	Same as predicate, except provides longer operating time
	Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock)	Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock)	Same as predicate
	Exergen: 9V alkaline	Exergen: 9V alkaline	Same as predicate
	Power Supply: 100-240 V AC, 2.0-1.0 A, 50-60 Hz, 65 W max, Class I	Power Supply: 100-240 V AC, 2.0-1.0 A, 50-60 Hz, 65 W max, Class I	Same as predicate
	NomoLine: 5V, 160mA typical, 800mA peak	NomoLine: 5V, 160mA typical, 800mA peak.	Same as predicate

Attribute	Predicate Device: SmartLinx Vitals Plus	Proposed Device: Capsule Vitals Plus	Discussion
Computing Platform	Neuron 2 PC running Windows 7 operating System	Neuron 2 PC running Windows 7 operating System	Same as predicate
		Neuron 3 PC running Windows 10 operating system	Essentially same as predicate
	Matte display screen	Neuron 2: Matte display screen	Same as predicate
		Neuron 3: Glossy display screen	Operationally equivalent. Verified and validated against the same specifications
	Resistive technology touch screen	Neuron 2: Resistive technology touch screen	Same as predicate
		Neuron 3: Capacitive technology touch screen	Operationally equivalent. Verified and validated against the same specifications

Discussion

The only difference between the proposed Capsule Vital Plus intended use and the predicate SmartLinx Vitals Plus intended use is the brand name. There are no differences in classification. The main battery for Neuron 3 is new but uses the same technologies as the predicate Neuron 2. The new touch screen and display technologies, hardware computing platform and operating system of the Neuron 3 have all been verified and validated according to standard protocol against the same specifications as the Neuron 2 and have been found to be operationally equivalent.

These differences between the proposed and predicate devices are not critical for the intended use of the proposed device, and do not affect the safety and effectiveness of the device when used as labeled.

Performance Testing

Performance testing assures that essential device characteristics have been appropriately implemented to provide safe and effective function and performance for the device's intended use. The performance testing consists of hardware and software verification and validation, as well as testing to FDA recognized consensus standards.

The Capsule Vitals Plus Patient Monitoring System conforms with FDA recognized consensus standards listed in *Table 4* below.

Table 4 FDA Recognized Consensus Performance Standards

FDA Recognition #	Standard Number	Standard Edition / Date	Title
19-4	ANSI AAMI ES60601-1	2005/(R)2012 and A1:2012	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-8	IEC 60601-1-2	Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5-89	IEC 60601-1-6	Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5-114	IEC 62366-1	Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices
13-79	IEC 62304	Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes

FDA Recognition #	Standard Number	Standard Edition / Date	Title
5-76	IEC 60601-1-8	Edition 2.1 2012-11	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
19-33	IEC 62133-2	Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
3-123	IEC 80601-2-30	Edition 2.0 2018-03	Medical electrical equipment Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers
6-421	ISO 80601-2-56	Second edition 2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
1-139	ISO 80601-2-61	Second edition 2017-12 (Corrected version 2018-02)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
1-140	ISO 80601-2-55	Second edition 2018-02	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
19-10	UL 1642	5th Edition	Lithium Batteries

FDA Recognition #	Standard Number	Standard Edition / Date	Title
19-11	UL 2054	2nd Edition	Household and Commercial Batteries
19-23	IEC 60086-4	Edition 4.0 2014-09	Primary batteries - Part 4: Safety of lithium batteries
2-220	ISO 10993-1	Fourth edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
5-40	ISO 14971	Second edition 2007/(R)2010	Medical devices - Application of risk management to medical devices
19-30	AIM Standard 7351731	Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

Clinical Studies

The subject of this premarket submission, Capsule Vitals Plus Patient Monitoring System, did not require clinical studies to support substantial equivalence.

Conclusions

Substantial equivalence of the proposed Capsule Vitals Plus Patient Monitoring System is demonstrated through performance testing and conformance with FDA recognized consensus standards. The proposed Capsule Vitals Plus Patient Monitoring System results in equivalent design, features and functionality as compared with the predicate device with few exceptions that do not raise any new questions of safety or effectiveness. Capsule Technologies therefore views the proposed Capsule Vitals Plus Patient Monitoring System to be eligible for a decision of substantial equivalence when compared to the predicate device, the SmartLinx Vitals Plus Patient Monitoring System.